UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 03-AUG-2005

Subject: **Difenoconazole** - Acute and Chronic Dietary Exposure Assessments.
PC Code: 128847. DP#: 319943. Decision#: 301882.

Reviewer: Sarah J. Levy, M.S., Chemist
Registration Action Branch 1/Health Effects Division (RAB1/HED; 7509C)

Through: Sheila Piper, Chemist
William Cutchin, Chemist
Dietary Exposure Science Advisory Council (DE SAC)

PV Shah, Ph.D., Branch Senior Scientist
RAB1/HED (7509C)

To: Sarah J. Levy, M.S., Risk Assessor
RAB1/HED (7509C)

Executive Summary

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 2.03) model. This model uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996 and 1998). These analyses were performed to support Section 3 registrations for the application of difenoconazole to barley, cotton, sweet corn, and tolerances for imported grapes and pome fruit.

Acute: The acute analysis assumed tolerance-level residues, 100% crop treated (CT), and DEEM™ (ver. 7.76) default processing factors for all proposed and registered commodities (Tier 1). The resulting acute food exposure estimates were less than HED's level of concern at the 95th percentile ($\leq$1.0% acute population-adjusted dose (aPAD) for females 13-49 years old; an acute endpoint was not established for the general U.S. population, including infants and children).

Chronic: The chronic analysis assumed tolerance-level residues for all proposed commodities, anticipated residues (ARs) for the previously-registered commodities, and 100% CT and DEEM™ (ver. 7.76) default processing factors for all commodities (partially refined, Tier 2 analyses). The resulting chronic food exposure estimates were less than HED's level of concern (≤16% chronic population adjusted dose (cPAD); children 1-2 years old were the most highly exposed population). A cancer dietary assessment was *not* conducted for difenoconazole because the cancer no-observable-adverse-effect- level (NOAEL) is higher than the chronic reference dose (RfD); therefore, the chronic dietary risk estimate is more protective.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (*i.e.*, the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the PAD. The PAD is equivalent to the RfD divided by the special Food Quality Protection Act (FQPA) Safety Factor (SF). For acute and chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the aPAD and cPAD, respectively.

The last dietary risk assessment for difenoconazole was conducted on 12-OCT-1999 (Memo, S. Chun, DP# 258775). The current acute and chronic dietary assessment is an update of the previous assessment conducted in 1999 (*i.e.*, the current commodities were added at the HED-recommended tolerance levels to the last dietary assessment).

II. Residue Information

Difenoconazole tolerances are published in 40 CFR§180.475.

Residues of Concern in Plants and Livestock: Table 1 is a summary of the HED Metabolism Assessment Review Committee (MARC) decisions concerning the residues of concern in plants, ruminants, and milk for tolerance expression and risk assessment purposes (no DP#, G. Kramer, meeting date 14-JUL-1994). Note, that the drinking water residue of concern for risk assessment purposes was decided by the difenoconazole risk assessment team (Memo, S. Levy, *et al.*, 23-NOV-1999; DP# 258774).

Table 1: Difenoconazole Residues of Concern in Plants and Ruminants.

Matrix	Residues of Concern	
	For Risk Assessment	For Tolerance Expression
Plants	Parent Only	Parent Only
Ruminant	Parent Only	Parent Only
Milk	Parent Only	Parent Only
Water	Parent Only	NA

Recommended Tolerances: Based on the residue chemistry data submitted with the current petitions, HED recommended for establishment of the food tolerances listed in Table 2 (DP# 307074, S. Levy, 03-AUG-2005):

Table 2: HED-Recommended Tolerances for Difenoconazole.

Commodity	Recommended Tolerance (ppm)
Grape	0.10
Fruit, pome, group 11	0.10
Barley, hay[1]	0.05
Barley, straw[1]	0.05
Barley, forage[1]	0.05
Cotton, undelinted seed	0.05
Cotton, gin byproducts	0.05
Corn, sweet, forage	0.01
Corn, sweet, stover	0.01
Corn, sweet, kernel plus cob with husks removed	0.01

[1] A tolerance is established at 0.10 ppm for imported barley grain.

Residues used in the Acute Analysis (see Attachment 2): The acute analysis assumed tolerance-level residues and 100% CT for all commodities. DEEM™ (ver. 7.76) default processing factors were assumed for all processed commodities.

Residues used in the Chronic Analysis (see Attachment 4): The chronic analysis assumed tolerance-level residues for all proposed commodities, ARs previously calculated for the registered commodities (see Attachment 1) and 100% CT and DEEM™ (ver. 7.76) default processing factors for all commodities (partially refined, Tier 2 analyses). Note that the meat and milk ARs that were previously calculated for the 1999 assessment had %CT incorporated directly into the residue input value.

Water Residues Used in the Analyses: The drinking water values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED; Memo, M. Janson, *et al.*, 02-MAY-2005; DP# 307166). EFED used the FIRST (version 1.0; Aug. 1, 2001) and SCI-GROW (Screening Concentration in Ground Water; version 2.3; Nov. 4, 2003) screening models to assess estimated drinking water concentrations (EDWCs) of difenoconazole in surface water and ground water, respectively. For surface drinking water, results from FIRST indicate that the peak (acute) concentration of difenoconazole is not likely to exceed 0.60 µg/L (ppb), and that the average annual (chronic) concentration is not likely to exceed 0.14 µg/L (ppb). For ground water, SCI-GROW indicates that difenoconazole concentrations are not likely to exceed 0.0008 µg/L (ppb). These value generally represent upper-bound estimates of the concentrations that might be found in surface water and groundwater due to the use of difenoconazole as a wheat, triticale, and canola seed treatment. Both models provide estimates that are suitable for screening purposes.

III. Program and Consumption Information

DEEM-FCID™ Program and Consumption Information: Difenoconazole acute and chronic dietary exposure assessments were conducted using the DEEM-FCID™ (ver. 2.03), which incorporates consumption data from USDA's CSFII (1994-1996 and 1998). The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*i.e.*, apple pie) are linked to EPA-defined food commodities (*i.e.*, apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (*i.e.*, orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (*i.e.*, those who reported eating relevant commodities/food forms) and a per-capita (*i.e.*, those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

IV. Toxicological Information

On 08-SEP-1998, HED's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base of difenoconazole and re-assessed the RfD established in 1994, as well as the toxicological endpoints for the dietary and occupational exposure risk assessments that were selected in 1994. At this meeting, the HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to difenoconazole as required by FQPA of 1996 (HED Doc. No. 012873, 25-SEP-1998). Shortly thereafter, the HED FQPA SFC met on 19-OCT-1998 and recommended that the default 10x FQPA Safety Factor (SF) be reduced to 1x when assessing acute and chronic dietary exposures (HED Doc. No. 012924, 28-OCT-1998). This decision is supported by recent OPP Guidance ("Determination of the Appropriate FQPA SF(s) in Tolerance Assessment," 2002), which recommends reduction of the 10x SF in cases where the degree of concern for susceptibility to infants and children is low, residual uncertainties in the database are low, and the overall confidence in the risk assessment is high. Difenoconazole is neither a developmental nor a reproductive toxicant; therefore, the degree of concern for pre- and postnatal toxicity is low. Moreover, there are no residual uncertainties in the toxicology database.

An acute dose and endpoint were not selected for the general U.S. population, including infants and children because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose).

For purposes of this action, HED recently reviewed HED's 27-JUL-1994 Cancer Peer Review Committee (CPRC) report (Memo, Jess Rowland and Esther Rinde) on difenoconazole and the supporting data-evaluation records (DERs). HED concluded that difenoconazole is a very weak carcinogen, showing effects only at excessive doses. In retrospect, the CPRC should have classified this pesticide as a category C with no linear quantification of cancer risk. The cRfD, based on borderline liver effects in male rats at 24.1 mg/kg and a NOAEL of 0.96 mg/kg, would certainly be protective of any carcinogenic effects seen in the mouse (Memo, S. Levy *et al.*, 05-AUG-2005; DP# 319944). Therefore, a cancer dietary assessment was *not* conducted for difenoconazole.

Table 3. Summary of Toxicological Doses and Endpoints of Difenoconazole.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 years old)	NOAEL = 25 mg/kg/day UF = 100 **aRfD** = 0.25 mg/kg/day	FQPA SF = 1x **aPAD** = aRfD/FQPA SF = 0.25 mg/kg/day	**Developmental Rabbit** -post-implantation loss, increased resorptions per doe, decreased fetal body weight
Acute Dietary (General population including infants and children)	An endpoint of concern attributable to a single exposure (dose) for the general population was not identified from the oral toxicity studies including the rat and rabbit developmental toxicity studies.		
Chronic Dietary (all populations)	NOAEL = 0.96 mg/kg/day UF = 100 **cRfD** = 0.01 mg/kg/day	FQPA SF = 1x **cPAD** = cRfD/FQPA SF = 0.01 mg/kg/day	**Chronic/Onco Rat** -cumulative decreases in body weight gains
Short-Term Dermal[1] (1-30 days)	oral NOAEL = 25 mg/kg/day	Residential LOC for MOE = 100	**Developmental Rabbit** post-implantation loss, increased resorptions per doe, decreased body weight
Intermediate-Term Dermal[1] (1-6 months)	oral NOAEL=1.25 mg/kg/day	Residential LOC for MOE = 100	**2-Generation Reproduction Rat** -based on decreased pup weight on day 21
Inhalation (Any time period)	None	Based on the low acute toxicity [Toxicity Category IV] , the application rate, the application method, and the number of applications, there is minimal concern for potential inhalation exposure/risk. This risk assessment is not required.	

[1] The HIARC estimated a dermal-absorption factor of 75% based on the LOAEL established for the same endpoint in the oral developmental toxicity study in rabbits and the 21-day dermal toxicity study in rabbits.

V. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the aPAD or cPAD, respectively. The following paragraphs are summaries of the DEEM-FCID™ (ver. 2.03) acute and chronic exposure analyses.

DEEM-FCID™: Acute and chronic analyses were performed using DEEM-FCID™ (ver. 2.03). DEEM-FCID™ (ver. 2.03) estimates the dietary exposure of the U.S. population and various population subgroups. The results reported in Tables 4 and 5 are for the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years old. The acute (95th percentile) and chronic dietary food exposure estimates were less than HED's level of concern (<100% aPAD and <100% cPAD, respectively) and are summarized in Tables 4 and 5 (see Attachments 3 and 5 for details).

Table 4: Summary of Acute Dietary Exposure and Risk for Difenoconazole at the 95th Percentile.

Population Subgroup[1]	aPAD (mg/kg/day)	Exposure (mg/kg/day)	%aPAD
Females 13-49 years old	0.25	0.001062	<1.0

[1] An endpoint attributable to a single exposure (dose) was not identified for the general U.S. population, including infants and children.

Table 5: Summary of Chronic Dietary Exposure and Risk for Difenoconazole.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	%cPAD
General U.S. Population	0.01	0.000240	2.4
All Infants (< 1 year old)		0.001004	10
Children 1-2 years old		0.001558	16
Children 3-5 years old		0.000933	9.3
Children 6-12 years old		0.000330	3.3
Youth 13-19 years old		0.000126	1.3
Females 13-49 years old		0.000121	1.2
Adults 20-49 years old		0.000120	1.2
Adults 50+ years old		0.000126	1.3

VI. Characterization of Inputs/Outputs

The acute analysis is highly conservative in that tolerance-level residues, DEEM™ default processing factors, and 100% CT were assumed. The acute analysis could be further refined through the use of ARs for all commodities, % market share data for the proposed commodities, %CT data for registered commodities, and/or processing factors for all commodities.

The chronic analysis assumed tolerance-level residues for all proposed commodities, ARs previously calculated for registered commodities, and 100% CT and DEEM™ (ver. 7.76) default processing factors for all commodities (partially refined, Tier 2 analyses). The chronic analysis could be further refined through the use of % market share data for the proposed commodities, and/or processing factors for all commodities.

VII. Conclusions

Acute and chronic dietary risk assessments were conducted using the DEEM-FCID™ (ver. 2.03) model. The acute analysis assumed tolerance-level residues, 100% CT, and DEEM™ (ver. 7.76) default processing factors for all proposed and registered commodities (Tier 1). The resulting acute food exposure estimate was less than HED's level of concern (≤1.0% aPAD for females 13-49 years old).

The chronic analysis assumed tolerance-level residues for all proposed commodities, ARs previously calculated for the registered commodities, and 100% CT and DEEM™ (ver. 7.76) default processing factors for all commodities (partially refined, Tier 2 analyses). The resulting chronic food exposure estimates were less than HED's level of concern (≤16% cPAD; children 1-2 years old were the most highly exposed population).

VIII. Attachments

Attachment 1: AR Table from Previous Difenoconazole Dietary Assessment (Memo, S. Chun, 12-OCT-1999; DP# 258775)
Attachment 2: DEEM-FCID™ Acute Residue File
Attachment 3: DEEM-FCID™ Acute Exposure Estimates
Attachment 4: DEEM-FCID™ Chronic Residue File
Attachment 5: DEEM-FCID™ Chronic Exposure Estimates

cc with all attachments: S. Levy (RAB1)
RDI: DESAC (15-JUL-2005)
S. Levy:806T:CM#2:(703)305-0783:7590

Attachment 1: AR Table from Previous Difenoconazole Dietary Assessment (Memo, S. Chun, 12-OCT-1999; DP# 258775)

Commodity	Residue Levels to Use in Chronic DEEM™ Analysis (ppm)
Bananas	0.01
Plantains	0.01
Canola	0.005
Wheat grain	0.005
Sweet Corn	0.005
Meat*	0.000014
Meat by-products (except kidney)*	0.00044
Kidney*	0.00012
Fat*	0.000041
Milk	0.000013
Poultry meat	0.000006
Poultry meat by-products (except kidney)	0.000023
Poultry kidney	0.000034
Poultry fat	0.0000030
Eggs	0.000019
Egg whites	0.0000043
Egg yolk	0.000046

* These ARs should be used for meat, fat and meat by-products of cattle, horses, goats, hogs, and sheep.

Attachment 2: DEEM-FCID™ Acute Residue File

U.S. Environmental Protection Agency Ver. 2.02
DEEM-FCID Acute analysis for DIFENOCONAZOLE
Residue file name: C:\difenoconazole_acute.R98
Analysis Date 07-28-2005 Residue file dated: 07-28-2005/11:11:07/8
Reference dose: aRfD = 0.25 mg/kg bw/day NOEL = 25 mg/kg bw/day

EPA Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
11000070	11	Apple, fruit with peel	0.100000	1.000	1.000	
11000080	11	Apple, peeled fruit	0.100000	1.000	1.000	
11000081	11	Apple, peeled fruit-babyfood	0.100000	1.000	1.000	
11000090	11	Apple, dried	0.100000	8.000	1.000	
11000091	11	Apple, dried-babyfood	0.100000	8.000	1.000	
11000100	11	Apple, juice	0.100000	1.200	1.000	
11000101	11	Apple, juice-babyfood	0.100000	1.200	1.000	
11000110	11	Apple, sauce	0.100000	1.000	1.000	
11000111	11	Apple, sauce-babyfood	0.100000	1.000	1.000	
95000230	O	Banana	0.200000	1.000	1.000	
95000231	O	Banana-babyfood	0.200000	1.000	1.000	
95000240	O	Banana, dried	0.200000	3.900	1.000	
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000	
15000250	15	Barley, pearled barley	0.100000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000	
15000260	15	Barley, flour	0.100000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000	
15000270	15	Barley, bran	0.100000	1.000	1.000	
21000440	M	Beef, meat	0.050000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.050000	1.000	1.000	
21000450	M	Beef, meat, dried	0.050000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.050000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.050000	1.000	1.000	
21000470	M	Beef, fat	0.050000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.050000	1.000	1.000	
21000480	M	Beef, kidney	0.050000	1.000	1.000	
21000490	M	Beef, liver	0.050000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.050000	1.000	1.000	
40000930	P	Chicken, meat	0.050000	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.050000	1.000	1.000	
40000940	P	Chicken, liver	0.050000	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.050000	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.050000	1.000	1.000	
40000960	P	Chicken, fat	0.050000	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.050000	1.000	1.000	
40000970	P	Chicken, skin	0.050000	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.050000	1.000	1.000	
15001260	15	Corn, pop	0.010000	1.000	1.000	
15001270	15	Corn, sweet	0.010000	1.000	1.000	
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000	
95001280	O	Cottonseed, oil	0.050000	1.000	1.000	
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000	
11001290	11	Crabapple	0.100000	1.000	1.000	
70001450	P	Egg, whole	0.050000	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.050000	1.000	1.000	
70001460	P	Egg, white	0.050000	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.050000	1.000	1.000	
70001470	P	Egg, yolk	0.050000	1.000	1.000	

70001471	P	Egg, yolk-babyfood	0.050000	1.000	1.000
23001690	M	Goat, meat	0.050000	1.000	1.000
23001700	M	Goat, meat byproducts	0.050000	1.000	1.000
23001710	M	Goat, fat	0.050000	1.000	1.000
23001720	M	Goat, kidney	0.050000	1.000	1.000
23001730	M	Goat, liver	0.050000	1.000	1.000
95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
24001890	M	Horse, meat	0.050000	1.000	1.000
11002100	11	Loquat	0.100000	1.000	1.000
28002210	M	Meat, game	0.050000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.010000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.010000	1.000	1.000
27022240	D	Milk, water	0.010000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.010000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.010000	1.000	1.000
11002660	11	Pear	0.100000	1.000	1.000
11002661	11	Pear-babyfood	0.100000	1.000	1.000
11002670	11	Pear, dried	0.100000	6.250	1.000
11002680	11	Pear, juice	0.100000	1.000	1.000
11002681	11	Pear, juice-babyfood	0.100000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
25002900	M	Pork, meat	0.050000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.050000	1.000	1.000
25002910	M	Pork, skin	0.050000	1.000	1.000
25002920	M	Pork, meat byproducts	0.050000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.050000	1.000	1.000
25002930	M	Pork, fat	0.050000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.050000	1.000	1.000
25002940	M	Pork, kidney	0.050000	1.000	1.000
25002950	M	Pork, liver	0.050000	1.000	1.000
60003010	P	Poultry, other, meat	0.050000	1.000	1.000
60003020	P	Poultry, other, liver	0.050000	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.050000	1.000	1.000
60003040	P	Poultry, other, fat	0.050000	1.000	1.000
60003050	P	Poultry, other, skin	0.050000	1.000	1.000
11003100	11	Quince	0.100000	1.000	1.000
29003120	M	Rabbit, meat	0.050000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.050000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.050000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.050000	1.000	1.000
26003410	M	Sheep, fat	0.050000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.050000	1.000	1.000
26003420	M	Sheep, kidney	0.050000	1.000	1.000
26003430	M	Sheep, liver	0.050000	1.000	1.000
50003820	P	Turkey, meat	0.050000	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.050000	1.000	1.000
50003830	P	Turkey, liver	0.050000	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.050000	1.000	1.000
50003840	P	Turkey, meat byproducts	0.050000	1.000	1.000

50003841	P	Turkey, meat byproducts-babyfood	0.050000	1.000	1.000
50003850	P	Turkey, fat	0.050000	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.050000	1.000	1.000
50003860	P	Turkey, skin	0.050000	1.000	1.000
50003861	P	Turkey, skin-babyfood	0.050000	1.000	1.000
86010000	O	Water, direct, all sources	0.000600	1.000	1.000
86020000	O	Water, indirect, all sources	0.000600	1.000	1.000
15004010	15	Wheat, grain	0.100000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.100000	1.000	1.000
15004020	15	Wheat, flour	0.100000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.100000	1.000	1.000
15004030	15	Wheat, germ	0.100000	1.000	1.000
15004040	15	Wheat, bran	0.100000	1.000	1.000

Attachment 3: DEEM-FCID™ Acute Exposure Estimates

U.S. Environmental Protection Agency Ver. 2.02
DEEM-FCID ACUTE Analysis for DIFENOCONAZOLE (1994-98 data)
Residue file: difenoconazole_acute.R98 Adjustment factor #2 used.
Analysis Date: 07-28-2005/11:12:50 Residue file dated: 07-28-2005/11:11:07/8
NOEL (Acute) = 25.000000 mg/kg body-wt/day
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
Daily totals for food and foodform consumption used.
Run Comment: ""

Summary calculations (per capita):

	95th Percentile			99th Percentile			99.9th Percentile	
Exposure	% aPAD	MOE	Exposure	% aPAD	MOE	Exposure	% aPAD	MOE
Females 13+ (preg/not nursing):								
0.001502	0.60	16643	0.002952	1.18	8468	0.002957	1.18	8453
Females 13+ (nursing):								
0.001149	0.46	21766	0.001381	0.55	18108	0.001445	0.58	17302
Females 13-19 (not preg or nursing):								
0.001261	0.50	19822	0.002085	0.83	11991	0.004269	1.71	5856
Females 20+ (not preg or nursing):								
0.001011	0.40	24723	0.001487	0.59	16812	0.002173	0.87	11502
Females 13-50 yrs:								
0.001061	0.42	23566	0.001585	0.63	15775	0.002768	1.11	9030
Females 13-49 yrs:								
0.001062	0.42	23529	0.001585	0.63	15768	0.002774	1.11	9011

Attachment 4: DEEM-FCID™ Chronic Residue File

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for DIFENOCONAZOLE 1994-98 data
Residue file: C:\difenoconazole_chronic.R98 Adjust. #2 used
Analysis Date 07-28-2005 Residue file dated: 07-28-2005/11:14:06/8
Reference dose (RfD) = 0.01 mg/kg bw/day
Comment:Chronic file

Food Crop Comment EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	#2
11000070	11	Apple, fruit with peel	0.100000	1.000	1.000
11000080	11	Apple, peeled fruit	0.100000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	0.100000	1.000	1.000
11000090	11	Apple, dried	0.100000	8.000	1.000
11000091	11	Apple, dried-babyfood	0.100000	8.000	1.000
11000100	11	Apple, juice	0.100000	1.300	1.000
11000101	11	Apple, juice-babyfood	0.100000	1.300	1.000
11000110	11	Apple, sauce	0.100000	1.000	1.000
11000111	11	Apple, sauce-babyfood	0.100000	1.000	1.000
95000230	O	Banana	0.010000	1.000	1.000
95000231	O	Banana-babyfood	0.010000	1.000	1.000
95000240	O	Banana, dried	0.010000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.010000	3.900	1.000
15000250	15	Barley, pearled barley	0.100000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000
15000260	15	Barley, flour	0.100000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000
15000270	15	Barley, bran	0.100000	1.000	1.000
21000440	M	Beef, meat	0.000014	1.000	1.000
21000441	M	Beef, meat-babyfood	0.000014	1.000	1.000
21000450	M	Beef, meat, dried	0.000014	1.920	1.000
21000460	M	Beef, meat byproducts	0.000440	1.000	1.000
21000461	M	Beef, meat byproducts-babyfood	0.000440	1.000	1.000
21000470	M	Beef, fat	0.000041	1.000	1.000
21000471	M	Beef,fat-babyfood	0.000041	1.000	1.000
21000480	M	Beef, kidney	0.000120	1.000	1.000
21000490	M	Beef, liver	0.000440	1.000	1.000
21000491	M	Beef, liver-babyfood	0.000440	1.000	1.000
40000930	P	Chicken, meat	0.000006	1.000	1.000
40000931	P	Chicken, meat-babyfood	0.000006	1.000	1.000
40000940	P	Chicken, liver	0.000023	1.000	1.000
40000950	P	Chicken, meat byproducts	0.000023	1.000	1.000
40000951	P	Chicken, meat byproducts-babyfoo	0.000023	1.000	1.000
40000960	P	Chicken, fat	0.000003	1.000	1.000
40000961	P	Chicken, fat-babyfood	0.000003	1.000	1.000
40000970	P	Chicken, skin	0.000034	1.000	1.000
		Full comment: Used the highest poultry AR from prev. assess.			
40000971	P	Chicken, skin-babyfood	0.000034	1.000	1.000
		Full comment: Used the highest poultry AR from prev. assess.			
15001260	15	Corn, pop	0.010000	1.000	1.000
15001270	15	Corn, sweet	0.010000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000
95001280	O	Cottonseed, oil	0.050000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000
11001290	11	Crabapple	0.100000	1.000	1.000
70001450	P	Egg, whole	0.000019	1.000	1.000

70001451	P	Egg, whole-babyfood	0.000019	1.000	1.000
70001460	P	Egg, white	0.000004	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.000004	1.000	1.000
70001470	P	Egg, yolk	0.000046	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.000046	1.000	1.000
23001690	M	Goat, meat	0.000014	1.000	1.000
23001700	M	Goat, meat byproducts	0.000440	1.000	1.000
23001710	M	Goat, fat	0.000041	1.000	1.000
23001720	M	Goat, kidney	0.000120	1.000	1.000
23001730	M	Goat, liver	0.000440	1.000	1.000
95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
24001890	M	Horse, meat	0.000014	1.000	1.000
11002100	11	Loquat	0.100000	1.000	1.000
28002210	M	Meat, game	0.000014	1.000	1.000
27002220	D	Milk, fat	0.000013	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.000013	1.000	1.000
27012230	D	Milk, nonfat solids	0.000013	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.000013	1.000	1.000
27022240	D	Milk, water	0.000013	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.000013	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.000013	1.000	1.000
11002660	11	Pear	0.100000	1.000	1.000
11002661	11	Pear-babyfood	0.100000	1.000	1.000
11002670	11	Pear, dried	0.100000	6.250	1.000
11002680	11	Pear, juice	0.100000	1.000	1.000
11002681	11	Pear, juice-babyfood	0.100000	1.000	1.000
95002830	O	Plantain	0.010000	1.000	1.000
95002840	O	Plantain, dried	0.010000	3.900	1.000
25002900	M	Pork, meat	0.000014	1.000	1.000
25002901	M	Pork, meat-babyfood	0.000014	1.000	1.000
25002910	M	Pork, skin	0.000470	1.000	1.000
Full comment: Used the highest cattle AR from prev. assess.					
25002920	M	Pork, meat byproducts	0.000440	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.000440	1.000	1.000
25002930	M	Pork, fat	0.000041	1.000	1.000
25002931	M	Pork, fat-babyfood	0.000041	1.000	1.000
25002940	M	Pork, kidney	0.000120	1.000	1.000
25002950	M	Pork, liver	0.000470	1.000	1.000
60003010	P	Poultry, other, meat	0.000006	1.000	1.000
60003020	P	Poultry, other, liver	0.000023	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.000023	1.000	1.000
60003040	P	Poultry, other, fat	0.000003	1.000	1.000
60003050	P	Poultry, other, skin	0.000034	1.000	1.000
Full comment: Used the highest poultry AR from prev. assess.					
11003100	11	Quince	0.100000	1.000	1.000
29003120	M	Rabbit, meat	0.000014	1.000	1.000
20003190	20	Rapeseed, oil	0.005000	1.000	1.000
Canola					
Full comment: Canola; AR					
20003191	20	Rapeseed, oil-babyfood	0.005000	1.000	1.000
Canola					
Full comment: Canola; AR					
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.000014	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.000014	1.000	1.000

26003400	M	Sheep, meat byproducts	0.000440	1.000	1.000
26003410	M	Sheep, fat	0.000041	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.000041	1.000	1.000
26003420	M	Sheep, kidney	0.000120	1.000	1.000
26003430	M	Sheep, liver	0.000440	1.000	1.000
50003820	P	Turkey, meat	0.000006	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.000006	1.000	1.000
50003830	P	Turkey, liver	0.000023	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.000023	1.000	1.000
50003840	P	Turkey, meat byproducts	0.000034	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	0.000034	1.000	1.000
50003850	P	Turkey, fat	0.000003	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.000003	1.000	1.000
50003860	P	Turkey, skin	0.000034	1.000	1.000
Full comment: Used the highest poultry AR from prev. assess.					
50003861	P	Turkey, skin-babyfood	0.000034	1.000	1.000
Full comment: Used the highest poultry AR from prev. assess.					
86010000	O	Water, direct, all sources	0.000140	1.000	1.000
Full comment: 0.14 ppb					
86020000	O	Water, indirect, all sources	0.000140	1.000	1.000
Full comment: 0.14 ppb					
15004010	15	Wheat, grain	0.005000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.005000	1.000	1.000
15004020	15	Wheat, flour	0.005000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.005000	1.000	1.000
15004030	15	Wheat, germ	0.005000	1.000	1.000
15004040	15	Wheat, bran	0.005000	1.000	1.000

Attachment 5: DEEM-FCID™ Chronic Exposure Estimates

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for DIFENOCONAZOLE (1994-98 data)
Residue file name: C:\difenoconazole_chronic.R98
Adjustment factor #2 used.
Analysis Date 07-28-2005/11:15:16 Residue file dated: 07-28-2005/11:14:06/8
Reference dose (RfD, Chronic) = .01 mg/kg bw/day
COMMENT 1: Chronic file

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000240	2.4%
U.S. Population (spring season)	0.000237	2.4%
U.S. Population (summer season)	0.000227	2.3%
U.S. Population (autumn season)	0.000250	2.5%
U.S. Population (winter season)	0.000247	2.5%
Northeast region	0.000280	2.8%
Midwest region	0.000240	2.4%
Southern region	0.000207	2.1%
Western region	0.000258	2.6%
Hispanics	0.000250	2.5%
Non-hispanic whites	0.000240	2.4%
Non-hispanic blacks	0.000231	2.3%
Non-hisp/non-white/non-black	0.000248	2.5%
All infants (< 1 year)	0.001004	10.0%
Nursing infants	0.000543	5.4%
Non-nursing infants	0.001178	11.8%
Children 1-6 yrs	0.001074	10.7%
Children 7-12 yrs	0.000293	2.9%
Females 13-19 (not preg or nursing)	0.000139	1.4%
Females 20+ (not preg or nursing)	0.000118	1.2%
Females 13-50 yrs	0.000141	1.4%
Females 13+ (preg/not nursing)	0.000178	1.8%
Females 13+ (nursing)	0.000161	1.6%
Males 13-19 yrs	0.000114	1.1%
Males 20+ yrs	0.000125	1.2%
Seniors 55+	0.000129	1.3%
Children 1-2 yrs	0.001558	15.6%
Children 3-5 yrs	0.000933	9.3%
Children 6-12 yrs	0.000330	3.3%
Youth 13-19 yrs	0.000126	1.3%
Adults 20-49 yrs	0.000120	1.2%
Adults 50+ yrs	0.000126	1.3%
Females 13-49 yrs	0.000121	1.2%

13544

R112336

Chemical:	**Difenoconazole**
PC Code:	**128847**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**08/03/2005**
File ID:	**DPD319943**
Accession Number:	**412-05-0099**

HED Records Reference Center
08/15/2005